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VI. Public Record

The EPA has established a public record of this testing decision (document control number OPTS–42041). This record includes:

(1) Federal Register Notice designating 1,3-dioxolane to the priority list and comments received in response thereto.

(2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal and comments received in response thereto.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Rm. E–107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received. (Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601)).

Dated: November 3, 1983.

William D. Ruckelshaus,

Administrator.

[FR Doc. 83–30534 Filed 11–10–83; 8:45 am]

BILLING CODE 6560–50–M

[OPTS–42040; TSH–FRL–2446–3]

Tris(2-Ethylhexyl)Trimellitate; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Eleventh Report of the Interagency Testing Committee (ITC) designated the chemical tris(2-ethylhexyl)-trimellite also known as trioctyltrimellitate (TOTM), for health and environmental effects testing consideration. The ITC suggested that a screening-type approach be utilized for TOTM before additional health effects studies are undertaken. Following the designation, plans for testing the health and environmental effects of TOTM were presented to EPA by the Chemical Manufacturers Association (CMA). The Agency has concluded tentatively that this program, when combined with related data from the CMA Phthalate Esters Program and the National Toxicology Program will supply screening information of the type that the ITC sought and is likely to provide information on which to reasonably predict the toxicity of TOTM. Therefore, at this time, the EPA is not initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require health or environmental effects testing of TOTM. This notice constitutes the Agency's response to the ITC's designation of TOTM, as mandated by section 4(e) of TSCA.

DATE: Comments should be submitted on or before December 29, 1983.

ADDRESS: Written comments should bear the document control number (OPTS–42040) and should be submitted in triplicate to: TSCA Public Information Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E–108, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–543, 401 M St., SW., Washington, D.C. 20460; Toll Free: (800–424–9065), In Washington, D.C. (554–1[illegible] Outside the USA: (Operator 202–[illegible]04).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94–469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations which require manufacturers and processors to test chemical substances and mixtures. Data developed through these test programs are used by EPA to determine the risks that such chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC may designate up to 50 of its recommendations at any time for priority consideration by EPA. EPA is required to respond within 12 months of the date of designation, either by initiating rulemaking under section 4(a) or publishing in the Federal Register reasons for not doing so.

The ITC designated TOTM for priority consideration in its Eleventh Report delivered to the Administrator of EPA on November 10, 1982, and published in the Federal Register on December 3, 1982 (47 FR 54624). The ITC recommended that industry first screen TOTM for chemical disposition and metabolism with identification of metabolites. If absorption and/or metabolism were shown to occur, the ITC suggested that reproductive effects and subchronic effects tests should be considered. The ITC also recommended that an evaluation of subchronic effects include assessments of hepatic peroxisomal proliferation and hypolipidemia. In addition, acute and chronic toxicity to fish and aquatic invertebrates were to be considered, as well as toxicity to plants, bioconcentration and chemical fate.

The reasons for the ITC's recommendations for health effects testing were: (1) The presumed structural relationship between TOTM and di(2-ethylhexyl)phthalate (DEHP), (2) the presence of the 2-ethylhexyl moiety in the molecule, and (3) projections of increasing usage of TOTM.

The ITC was concerned about toxicity to aquatic organisms and plants because of its view that: (1) TOTM was expected to be released to the aquatic environment and persist in sediments, (2) TOTM has a potential to bioaccumulate and possibly

contaminate the food chain, and (3) there is a possibility for the resuspension of TOTM from sediments in the aquatic environment through natural or human activities such as storms and dredging. Chemical fate testing was recommended to better characterize the transformations and persistence of TOTM in the aquatic environment. The bioconcentration testing recommendation was based on the relatively high estimated octanol/water partition coefficient of TOTM, which indicated a potential for bioconcentration.

Subsequent to the ITC Report, the Trimellitate Esters Panel (TEP), a group formed under the sponsorship of the Chemical Manufacturers Association (CMA) which includes the principal producers of TOTM and the supplier of the starting material, trimellitic anhydride, provided the EPA with information on production, exposure, uses, and release of TOTM (Refs. 3 and 9). EPA has considered these data and additional data reported by manufacturers under TSCA sections 8(a) and 8(d) in conjunction with other information in making its decision on TOTM.

II. Assessment of Exposure and Health and Environmental Effects.

A. Production, Use and Exposure

Tris(2-ethylhexyl)trimellitate (CAS No. 3319–31–1) or TOTM, is a clear to pale yellow viscous liquid with a faint odor. It has very low vapor pressure and low water solubility (Ref. 5).

TOTM is produced by the esterification of trimellitic anhydride with 2-ethylhexanol. Annual production is in the range of 20 to 25 million pounds (Ref. 3).

TOTM is used primarily as a specialty plasticizer in polyvinyl chloride (PVC) where stability at high temperatures, low volatility, low migration characteristics, and very high resistance to water extraction are required (Ref. 4). More than 90 percent of the annual production is used in 90°C and 105°C insulation for industrial grade electrical wire and cable (Ref. 3). The other significant uses of TOTM are as a specialty platicizer in refrigerator gaskets, roofing membranes and automotive crash pads (Ref. 3).

TOTM is produced through a closed system batch process. The American Conference of Governmental Industrial Hygienists (ACGIH) has established a TLV–TWA for trimellitic anhydride (TMA) of 0.005 ppm (Ref. 1). The engineering controls necessary to keep exposure to TMA within this limit also minimize occupational exposure to TOTM during its manufacture (Ref. 8). Worker exposure is limited in duration and occurs only at sampling, filter change, and loading. Similarly, based on the processes and controls in use by the industry, worker exposure to TOTM during processing is reported to be very limited (Ref. 3).

Exposure from consumer uses of TOTM are expected to be quite low because of its low vapor pressure, low water solubility, and low migration characteristics. The market for the jacketed wire is quite specialized; 105° and 90° UL listed wire is used in computers, electronic equipment and communications equipment. Most of the wire is bundled and enclosed either in metal conduits or in plastic jackets made with a different plasticizer, further limiting exposure potential (Ref. 9).

B. Health Effects Data

The acute oral toxicity (LD_{50}) of TOTM was reported to be greater than 3,200 mg/kg for both rats and mice (Ref. 5). The dermal LD_{50} for guinea pigs was greater than 20 ml/kg, and TOTM caused slight skin irritation in guinea pigs and slight eye irritation in rabbits (Ref. 5). In a 6-hour inhalation study, TOTM was found to cause minimal irritation to rats at a concentration of 230 mg/m^3 and was lethal at concentrations of 2,640 and 4,170 mg/m^3 (Ref. 5). In another acute inhalation study, TOTM had little or no effect in rats at 2,588 mg/m^3 for 4 hours (Ref. 3).

Ames assay testing produced negative results when TOTM was tested against five strains of *Salmonella* (Ref. 3). The Ames test also produced negative results with urine from rats given a single dose of 2,000 mg/kg of TOTM (Ref. 3). In addition, the Food and Drug Administration reported the results of two studies (Ref. 10) in its approval of TOTM for use as a plasticizer for PVC anticoagulant storage bags. In those studies, TOTM was found to be not mutagenic in a dominant lethal chromosome induction test in white Swiss mice and negative in a lung adenoma assay in Type A mice.

In a 28-day hepatotoxicity study, make Fischer-344 rats received 1,000 mg/kg/day of TOTM. At the end of the dosing period, animals receiving TOTM had statistically significant lowering of triglyceride levels compared to controls but no other effects were noted (Ref. 7).

In another TOTM study, two rhesus monkeys were infused with fifty ml. of plasma containing either ^{14}C-ring-labeled or ^{14}C-carbonyl-labeled TOTM (Ref. 6). Blood, urine and feces samples were collected for up to 2 weeks following dosing. The disappearance half-life from the blood was 10 minutes for the ring-labeled TOTM and 12 minutes for the carbonyl-labeled TOTM. Within 24 hours, 83 percent and 1 percent of the ring label and 78.4 percent and 2.3 percent of the carbonyl label were excreted in the urine and feces, respectively. Metabolites were not identified.

C. Environmental Effects Data

No information is available on the environmental effects of TOTM and little information is available on its environmental fate. Based on its low water solubility and high estimated log P value, it is likely to adsorb to soil readily (Ref. 8). The compound does not hydrolyze in water at neutral pH and is stable at high temperatures (Ref. 5). Based on its physical and chemical properties, TOTM is expected to partition to the terrestrial compartment rather than the atmospheric or aquatic compartments and is likely to be resistant to rapid chemical, biological or photochemical degradation (Ref. 8).

III. Ongoing Testing of Related Compounds

Because of concern about the potential toxicity of the 2-ethylhexyl moiety, the National Toxicology Program (NTP) has selected 13 compounds containing that group for toxicologic testing (Ref. 2). All 13 chemicals were negative in four different strains of *Salmonella* both with and without activation. Two of the compounds were also tested for chromosomal aberrations and found to be weakly positive. The same two compounds were evaluated in the sister chromatid exchange assay using Chinese hamster ovary cells and found to be negative. In addition, four of the compounds have been tested for carcinogenicity by the NTP, and two were found to be hepatocarcinogens. Currently, 2-ethylhexanol and mono(2-ethylhexyl) phthalate have been recommended for carcinogenicity testing. NTP is planning additional genotoxicity testing for 10 more 2-ethylhexyl compounds, including TOTM.

The CMA, on behalf of the Phthalate Esters Program Panel (PEPP), is conducting testing on the phthalate esters, alkyl diesters of 1,2-benzenedicarboxylic acid, which are primarily used as plasticizers. The CMA's proposal was accepted by the Agency in lieu of a test rule under section 4 of the Toxic Substances Control Act and is described in the Federal Register of October 30, 1981 (45 FR 53775).

Industry's phthalate testing program examines aquatic toxicity,

environmental transport and fate, and biodegradation of the high production alkyl phthalates and benzyl butyl phthalate. The program also examines, in a more experimental approach, potential oncogenic and mutagenic effects of selected alkyl phthalates and benzyl butyl phthalate. Basically, CMA's health program is a multistage test program consisting of two first-stage components: (1) A battery of short-term mutagenicity tests; and (2) a 21-day *in vivo* test with rats. CMA will concurrently be performing extensive metabolism work on di-2-ethylhexyl phthalate. Long-term tests, such as 2-year bioassays, will also be performed depending on the results of the short-term tests for other phthalates.

IV. Ongoing and Planned Testing of TOTM

The Trimellitate Esters Panel (TEP) has presented to EPA a proposal for testing TOTM for health effects, environmental effects and chemical fate which is conceptually similar to the program being performed by the PEPP, which the Agency previously found appropriate for assessment of the effects of a somewhat structurally related class of chemicals. The TEP proposal for TOTM includes the following tests:

1. *Mutagenicity.* To characterize further the genetic activity of TOTM, the TEP will perform two other short term tests in addition to those which have already been conducted: an unscheduled DNA synthesis assay in primary rat hepatocytes and a Chinese hamster ovary hypoxanthine quanine phosphoribosyl transferase point mutation test.

2. *Chemical disposition and metabolism.* Eastman Kodak is currently conducting *in vivo* and *in vitro* metabolism studies using TOTM. The rate of hydrolysis of TOTM was investigated in intestinal homogenates prepared from Sprague-Dawley rats. No measurable hydrolysis was observed (Ref. 3). In another study, rats were given a 100 mg/kg dose of TOTM ^{14}C-labeled on the ethylhexyl portion of the molecule. After 144 hours, the label was found to be distributed as follows: 74.9 percent in feces, 15 percent in urine, 2 percent in breath and 0.38 percent in carcass. Evidence such as this, that TOTM is absorbed into the body, was the first step in the screen proposed by the ITC. The identification of metabolites is still being investigated (Ref. 3). When results and conclusions of this work are available, they will be submitted to the Agency.

3. *28-Day feeding study.* The TEP is proposing a 28-day feeding study which will included examination of major organs and neurological tissues, full clinical chemical and hematological profiles, and investigation of peroxisome induction and hypolipidemia according to the method developed by the PEPP. This follows the suggestion of the ITC that peroxisome proliferation and hypolipidemia be used as screening factors for compounds containing the 2-ethylhexyl moiety.

4. *Physical-chemical properties.* The TEP proposes to develop a suitable analytical method for measuring TOTM in water. Using this procedure, they will then measure the maximum solubility of TOTM in water and the octanol/water partition coefficient, a predictor of bioconcentration potential.

5. *Biodegradation.* TOTM will be tested in a shake-flask biodegradation test to determine the rate of parent compound disappearance and CO_2 evolution, as well as the percentage of carbon converted to CO_2.

6. *Toxicity to aquatic invertebrates.* A 21-day reproduction study in *Daphnia magna*, the species most sensitive to DEHP, will be useful in assessing the environmental impact of TOTM. Acute toxicity data will be generated from the range-finding studies done in preparation for this study. Plant studies are not being considered at this time because of the low levels of exposure to TOTM. Should any data obtained in the initial testing indicate a need for additional information, further testing will be pursued.

The Trimellitate Esters Panel has submitted preliminary testing laboratory selections and protocols for tests to the Agency. The protocols for these studies have been reviewed by EPA scientists and, with minor exceptions, are acceptable. They are also available for examination in the public record of this proceeding.

Taking into account the time it will take for the Agency to evaluate public comments on its program, and assuming Agency approval, the TEP has proposed the following schedule. The mutagenicity studies are scheduled to begin in July 1984 and be completed (final report submitted) in January 1985. The 28-day feeding study will also begin in July 1984, with completion scheduled for June 1985. The development of an analytical method to measure TOTM in water will begin in July 1984 and be completed by October 1984. Using that method, the water solubility and octanol/water partition coefficient determinations will then begin and be completed in February 1985. The shake-flask CO_2 study is planned from February through June 1985 and the daphnid chronic exposure study from March through September 1985. All final reports will be submitted by October 1985. Program reviews will be conducted by EPA at appropriate intervals throughout the program to assess the need for additional testing of TOTM. Should TEP fail to make a good faith effort to adhere to its testing schedule outlined above, EPA may initiate rulemaking to require testing.

The TEP has furnished EPA with the names and addresses of the laboratories conducting the tests under this agreement. The TEP has also agreed to adhere to the Good Laboratory Practice Standards issued by the U.S. Food and Drug Administration as published in the Federal Register of December 22, 1978 (43 FR 59986). The TEP has agreed to permit laboratory inspections and study audits in accordance with the provisions outlined in TSCA section 11 at the request of authorized representatives of the EPA for the purpose of determining compliance with this agreement. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to Good Laboratory Practice provisions.

The TEP has further agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of each study will be retained for at least 10 years from the date of publication of the acceptance of any protocols by EPA and made available during an inspection or submitted to EPA if requested by EPA or its designated representative. Documentation which will be retained includes correspondence and other documents relating to the conduct, interpretation, or evaluation of data other than that included in the final report. The TEP understands that the Agency plans to publish quarterly in the Federal Register a notice of the receipt of any test data submitted under this agreement. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, any data submitted will be made available by EPA for examination by any person.

Finally, the TEP understands that failure to conduct the testing according to the specified protocols and failure to follow Good Laboratory Practice procedures may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to require further testing.

V. Decision Not To Initiate Rulemaking

The ITC was concerned about the health effects of TOTM primarily because of its structural similarity to DEHP and the presence of the 2-ethylhexyl moiety in the TOTM molecule. Concern about the toxicity of the 2-ethylhexyl moiety will be directly addressed in the NTP testing program. In addition to the testing already completed, 2-ethylhexanol and mono(2-ethylhexyl)phthalate, which are structurally similar to TOTM, will be tested for carcinogenesis, and 10 other 2-ethylhexanol compounds will be tested for genotoxic effects. This additional information on structurally similar substances may significantly contribute to the Agency's ability to predict the toxic effects of TOTM.

EPA believes that pursuing the TEP proposed testing program for mutagenic, subchronic and environmental effects, together with the data resulting from ongoing studies on related substances sponsored by the Phthalate Esters Panel, will provide the type of screening data the ITC recommended obtaining. Included among these data will be the identification of the metabolites of TOTM. When data are available upon completion of the testing planned by NTP and the testing proposed by the CMA Trimellitate Esters Panel, along with data gathered in the PEPP studies, a complete assessment of further testing needs for TOTM and its metabolites will be made. For these reasons, EPA has decided not to initiate rulemaking under section 4(a) of TSCA to require testing of TOTM at this time.

VI. References

(1) ACGIH. 1982. American Conference of Governmental Industrial Hygienists. TLVs ®. Threshold limit values for chemical substances in work air adopted by ACGIH for 1982. Cincinnati, OH: ACGIH, pp. 32–33.

(2) Canter, D. A. 1983. National Toxicology Program, U.S. Department of Health and Human Services. Memorandum to Members, Chemical Evaluation Committee and Liaison Staff. Subject: Nomination of Additional Compounds Containing the 2-Ethylhexyl Moiety for NTP Testing.

(3) Chemical Manufacturers Association. 1983. (June 13, 1983) Tris(2-ethylhexyl)trimellitate: A Voluntary Testing Program under Section 4 of the Toxic Substances Control Act.

(4) Dougherty PC, Cassis FA. 1962. Amoco Chemicals Corporation. Vinyl plasticizers from trimellitic anhyride. Soc. Plast. Eng. Tech. Pap. 18 (session 22):1–9.

(5) Eastman Chemical Products, Inc. 1982 (Feb.) Product literature. KODAFLEX ® TOTM. Trioctyl trimellitate (tri[2-ethylhexyl]trimellitate). Coatings Chemicals Division, B–280, Kingsport, TN 37662.

(6) Kevy, S. V., Jacobson, N. S., and Harmon, W. E., "The Need For a New Plasticizer For Polyvinyl Chloride Medical Devices," Trans. Am. Soc. Artif. Intern. Organs, Vol. XXVII, pgs. 296–390, 1981.

(7) Nuodex, Inc. 1981. 28 day hepatotoxicity study in rats conducted for Tenneco Chemicals, Incorporated with samples NUOPLAZ TOTM and NUOPLAZ DOP. 878220032.

(8) Spangler, W. J. Capital Systems Group, Inc. and Dynamac Corporation. 1983. Final technical support document: Tris(2-ethylhexyl) trimellitate. Washington, D.C.: Office of Pesticides and Toxic Substances. U.S. Environmental Protection Agency. Contract no. 68–01–6530.

(9) USEPA. 1982. U.S. Environmental Protection Agency. Meeting Summary—Meeting with CMA Subcommittee on TOTM—January 18, 1983. Arlington, VA.

(10) USFDA. 1981. U.S. Food and Drug Administration. Summary for Basis of Approval BB—NDA 80–77/04. Washington, D.C.

VII. Public Record

The EPA has established a public record of this testing decision (docket number OPTS–42040). This record includes:

(1) Federal Register notice designating TOTM to the priority list and comments received thereon.

(2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data, including the references cited above.

(5) Federal Register notice requesting comment on the negotiated testing proposal and comments received in response thereto.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Rm. E–107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: November 3, 1983.

William D. Ruckelshaus,

Administrator.

[FR Doc. 83–30535 Filed 11–10–83; 8:45 am]

BILLING CODE 6560–50–M

[OPTS–42039; BH–FRL 2450–3]

Bis(2-Ethylhexyl)Terephthalate; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notic

SUMMARY: Eleventh Report of the Interagen sting Committee (ITC) designat s(2-ethylhexyl)-tereph e, also known as dioctyl tereph te (DOTP), for health and envir mental effects testing consideration. Subsequent to the ITC designation, Eastman Kodak Company presented to EPA a testing program for the health and environmental effects testing of DOTP. Also, the National Toxicology Program (NTP) has nominated a variety of chemicals containing the 2-ethylhexyl moiety and 2-ethylhexanol for toxicity testing. The Agency has concluded that these programs are sufficient to evaluate the health and environmental effects of DOTP as recommended for testing by the ITC and is not initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) at this time. This notice constitutes the Agency's response to the ITC's designation of DOTP, as mandated by section 4(e) of TSCA.

DATE: Interested persons are invited to comment on this proposed decision. All comments should be submitted on or before December 29, 1983.

ADDRESS: Written comments should bear the document control number (OPTS–42039) and should be submitted in triplicate to: TSCA Public Information Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room E–108, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Room E–543, Washington, D.C. 20460; Toll Free: (800–424–9065), Outside the USA: (Operator 202–554–1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94–469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations which require manufacturers and processors to test chemical substances and mixtures. Data developed through these test programs are used by EPA to assess the risks that such chemicals may present to health and the environment. Section 4(e) of (TSCA) established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the